

REMARKS

The Examiner is thanked for withdrawing the final rejection and entering the submission of June 4, 2010. The withdrawal of the rejection of claim 10 under 35 U.S.C. §112, second paragraph, has been noted.

Claims 8 and 10-13 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over Lieberman in view of Ullman et al. (Ullman) and Geller.

Reconsideration is requested.

Lieberman was cited as teaching a pharmaceutical tablet with layers and teaches that it is known to have a tablet where the center layer is free of active. Lieberman was also cited as teaching that it is known to place scores on tablets to allow for manual breakage and the Examiner acknowledged that Lieberman noted that traditional scores result in significant variation in drug doses. The Examiner also acknowledged that Lieberman fails to "directly teach" a tablet with only two layers or the location of the score or of the active ingredient.

The Examiner did not acknowledge that the portion of Lieberman on page 274 does not disclose a score on the three layer tablet. Lieberman's mention of a scored tablet at page 172 of Lieberman is not connected to the disclosure of the three layer tablets disclosed at page 274. If Lieberman intended to teach scoring a three layer tablet, he would not have addressed this issue in sections of his book that related to the three layered tablets. It also would not be consistent with a teaching regarding "breaking into equal parts" because unless the break took place in the inert portion of the tablet (which he doesn't teach), the break of the three layer tablet would not necessarily result in equal parts.

Ullman was applied as teaching a multi-fractionable unitary tablet structure and a score which traverses the entire tablet.

Geller was applied as teaching deeply scored tablets where the active ingredient is isorbide dinitrate. Geller also noted that scores do not always assure precise division of the tablet.

No contention has been raised that either Ullman or Geller teach or suggest a two layered tablet as only a single layer or homogeneous tablet structure is disclosed by Ullman and Geller.

It should be noted while both Lieberman and Geller acknowledged the problem of imprecise tablet splitting, neither suggest any solution for the problem. Additionally, no reason has been advanced to support a thesis that a single layer tablet suggests a two layer tablet. The text of claim 8 is limited to a two layer tablet and this is not suggested by any of the cited references.

The different considerations that arise from the breaking of a layered tablet versus the breaking of an unlayered tablet point to the unobviousness of the claimed invention as compared to the different concepts set forth in Lieberman, Ullman and Geller. Each of the cited references describe tablet structures that are made differently for different purposes. The concept of the present invention is not found in any of the cited references.

The argument that one would remove one of the drug layers of Lieberman if one would desire to deliver only one of the actives does not address the fact that no one who is skilled in the art would make a two layered tablet with one inactive layer by removal of one active layer from the Lieberman tablet. If one active is desired, one would make a homogeneous tablet in the manner taught by Geller and no one

would attempt to deconstruct the Lieberman tablet if only one active was to be made.

It can be readily appreciated and understood from the present application, that breaking the tablet through the inert layer provides for very accurate breaking of a tablet. This information cannot be used to modify what is taught in the prior art as it reflects the applicants' contribution. The cited prior art does not disclose a two layer-scored tablet as defined in claim 8 where the score extends at least 70% of the distance into the active layer.

The present rejection is not based on the contents of the cited reference. No explanation has been given as to where in the references any disclosure is found that tells the skilled artisan to keep a separating layer on a tablet when the reason for its presence no longer exists because there is no incompatible third layer.

It is a fundamental concept in patent law that isolated teachings may not be extracted from a reference and combined with unsupported contentions as to what a skilled person in the art would be motivated to do. In the present case, the prior art used the inert layer for one purpose and only one purpose, namely to separate incompatible active drugs. Since claim 8 excludes any incompatible layer, there is no reason that supports the argument that Lieberman provides a direction or motivation to deconstruct the three layer tablet and retain one active layer with the inert layer.

The Examiner has cited *In re Larson*, 144 USPQ 347 (CCPA 1965) and *In re Kuhle*, 188 USPQ 7 (CCPA 1975) as authority for the argument that it would be obvious to eliminate one active layer from the Lieberman three layer tablet as the elimination of a structural component and its function was obvious. This argument is not applicable to a situation where removal of an element and its function also removes the reason why an added structural element, namely an

inert layer that is only required for the separation of two incompatible active agents is no longer necessary. No one of ordinary skill in the art would make a single active layer tablet by deconstructing a three layer tablet and there has been no demonstration that such a deconstruction could be carried out.

Claim 8 points out a tablet which is distinguishable from Lieberman, Ullman and Geller because claim 8 points out a scored tablet having two segments, one of which has no active ingredient and has a score in the active segment where the score extends at least 70% of the distance to the second segment. This concept is not disclosed or suggested by Lieberman, Ullman or Geller as the tablets disclosed by these references are either three layer tablets or one layer tablets.

The language of claim 8, part (a) points out the claimed tablet consists of two segments which excludes the three layered tablets of Lieberman who does not make a two layered tablet obvious. Geller is only concerned with a single layer tablet and does not disclose the benefit of being able to break a tablet where there is a deeply scored active layer and an inert lower layer which results in a more equal division of the active component.

As noted above, Claim 8 and the claims that are dependent on claim 8 point out a structure where there are two segments, one of which is inactive and there is a minimum distance into the active layer for the score, where the distance is specified as being at least 70% of the distance from the top surface to the interface between the two segments. There is no reason to modify Lieberman with the Geller score technique because Geller is concerned with making a single layer tablet with one active ingredient and does not suggest a two layered tablet where the score is a minimum of 70% of the distance from the top of the tablet to a second inert segment. If one were to deeply score the

Lieberman tablet, one would not obtain the benefits of the deep score taught by Geller. This is evident from the fact that in a three layer tablet, the presence of a deep score would have no effect on the third layer based on the Geller teaching that the score should not extend more than 2/3 of the way through the tablet which in the case of the Lieberman tablet, would not allow the break to occur in the inactive layer.

Claims 8-12 were provisionally rejected for obviousness double patenting over copending application Serial No. 10/598,355.

A terminal disclaimer is attached to this Request for Reconsideration in order to obviate the provisional double patenting rejection.

Respectfully submitted,



James V. Costigan
Registration No. 25,669

Hedman & Costigan, P.C.
1230 Avenue of the Americas
7th Floor
New York, NY 10020-1512
(212) 302-8989